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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,411	03/12/2001	Jan Tadeusz Czernuszka	480821.90043	1013

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Office Action Summary

Application No.

09/720,411

Applicant(s)

CZERNUSZKA ET AL.

Examiner

Gollamudi S Kishore, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-12,14-16,18-23,25-30 and 34-38 is/are pending in the application.
- 4a) Of the above claim(s) 18-20 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-12,14-16,21-23,26-30 and 34-38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

The amendment dated 4-12-04 are acknowledged.

Claims included in the prosecution are 1-2, 6-12, 14-16, 21-23, 26-30 and 34-38. Claims 18-20 and 25 remain withdrawn.

Claim Rejections - 35 USC ' 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-2, 6-12, 14-16, 21-23, 26-29 and 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 479 582 of record in combination with either of Eanes (Bone and Mineral, 17, pp., 269-272, 1992 of record) or Eanes (Calcif. Tissue Int (40, pp 43-48, 1987, also of record) in further combination with Chung (5,039,546).

EP discloses multilamellar liposomes containing an antibiotic. The liposomes are suspended in hydroxy apatite (hydroxy -calcium phosphate). The compositions are useful as dental implants (note the abstract, columns 4-7 and claims). What is lacking in EP is the teaching of the coating of the liposomes with

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apatite (calcium phosphate) instead of hydroxy-apatite. What are also lacking in EP are the teachings of the attachment of the liposomes to a surface.

As pointed out in the previous action, Eanes in both publications discloses liposomes coated with calcium phosphate; liposomes are made of phosphatidylcholine. The liposomes are suspended in NaCl and therefore, the surface layer containing chloride ions as recited in claim 6 is inherent in the prior art composition (note the abstract, and Table 1 on page 270 in Bone and Mineral; summary, Materials and Methods and discussion in Calcif. Tissue Int.). What is lacking in Eanes is the explicit teaching of the thickness of the coating of the vesicles by the calcium phosphate. However, on page 270, Eanes appear to suggest that the coating on the external surface is time dependent and PL dependent and therefore, it would have been obvious to one of ordinary skill in the art to obtain the vesicles with a desired coating thickness by varying the time and the selection of suitable phospholipids.

In essence, Eanes teaches the formation of coatings of calcium phosphate on the liposomal surface when suspended in calcium phosphate solutions.

Chung discloses that for dental implants (ceramic or metal) coated with either hydroxy apatite or calcium phosphate are known and routinely used in dental and orthopedic areas (note the abstract, columns 1-2 and claims).

The use of calcium phosphate instead of hydroxy apatite in EP would have been obvious to one of ordinary skill in the art since Eanes teaches that the liposomes can be coated with calcium phosphate and Chung teaches that both hydroxy apatite and calcium phosphates are routinely used in dental implant

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area. Further coating the composition of EP over a substrate would have been obvious to one of ordinary skill in the art, with a reasonable expectation of success since Chung teaches that either hydroxy apatite or apatite are coated on a substrate for use in dental and orthopedic areas. Chung does not disclose specifically the sizes of the implants. However, it is deemed to be within the skill of the art to use the desired sizes since sizes depend on the site the implant is to be used.

3. Claims 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 479 582 of record in combination with either of Eanes (Bone and Mineral) or Calcif. Tissue Int., cited above and Chung (5,039,546), further in view of Redepenning (5,310,464).

The teachings of EP, Eanes and Chung have been discussed above. Chung in particular teaches the coating of calcium phosphate on metal or ceramic implants. What is lacking in the cited prior art is that the process of coating be conducted electrolytically.

Redepenning discloses that when the metallic implants are coated by electrolytic process, the coating is superior to the coating obtained by conventional processes. Redepenning's process involves immersing the implant in a solution of calcium and dihydrogen phosphate and coating the implant by electrolysis (note the abstract, col. 3, line 38 et seq; and claims).

The use of electrolysis for the coating of liposomes containing an outer layer of calcium phosphate over a metallic implant would have been obvious to

one of ordinary skill in the art because Redepenning teaches that electrolytic process is superior to the conventional processes.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's only arguments are based on the declaration previously provided. Applicant argues that the declaration makes it clear that the process of the prior art references could not produce the invention of claim 1 and in particular, the processes of Eanes would puncture the walls of the vesicles thereby making the containment of a pharmaceutically active agent within the vesicle impossible. This argument is not found to be persuasive since there is nothing in Eanes to indicate that the hydroxy apatite, which is outside made the entrapped antibiotic to leak out. Since applicant is questioning the teachings of the prior art, the burden is therefore upon applicant to show that the entrapped antibiotic leaks out because the process is different and applicant has not provided any experimental evidence to dispute the teachings of the prior art. Secondly, as previously pointed out, instant claims do not recite any specific amounts of the active agent encapsulated in the vesicles.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

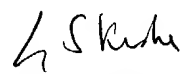
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action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM-4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Gollamudi S Kishore, PhD
Primary Examiner
AV 1615